K112511
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2.0 510(k) Summary

DOBBHOFF™ Dual Port Feeding Tubes

In accordance with section 513(i) of the SMDA and as defined in 21 CFR Part 807.92 this summary is submitted by:

Covidien

15 Hampshire Street

Mansfield, MA 02048

Date Prepared: August 23, 2011

a. Contact Person

Debora Stapleton
Manager, Regulatory Affairs
Covidien
Telephone: (508) 452-4866
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: Tubes, gastrointestinal

Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Trade Name: *Dobbhoff™ Dual Port Feeding Tubes*

c. Identification of Legally Marketed Device(s)

- Dobbhoff™ Feeding Tubes with Hydromer Lubricant were most recently cleared under notification K831868.
- Corpak Medsystems Corflo® Enteral Feeding Tubes were most recently cleared under notification K083210.

d. Device Brief Description

The DOBBHOFF nasogastric enteral feeding tubes are small bore enteral access catheters. These feeding tubes include an external proximal access port for connection to enteral feeding sets and to oral tip, enteral syringes. The tubing is constructed with a radiopaque material and with a hydrophilic coating to assist with insertion of the tube and, if a stylet was in place during tube insertion, to assist with removal of the stylet. The stylet is made of specially designed metal wire which may be optionally utilized to assist with tube

placement. The tubes are each equipped with external markings in units of centimeters to assist in measuring the amount of tube inserted into the alimentary tract.

e. Device Intended Use

Enteral feeding provides nutritional support for patients who require feedings of liquids as a substitute for solid food. These enteral access devices are to be inserted via natural naso/oro-enteric passages and intended for the transfer of nutritional and hydrating fluids, as well as medications, into the alimentary tract.

f. Product Comparison

The proposed and predicate catheters are all intended for patients who require feedings of liquids as a substitute for solid food. These products are catheters that have the same intended use, the same function, the same general technological characteristics, and are for connection to the same types of devices.

g. Nonclinical Testing

The enteral feeding catheters have been evaluated against the design and standard performance specifications of *EN1615:2000, Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing*. Biocompatibility testing has demonstrated that the proposed device meets guidelines presented in ISO 10993-1:2009, with the FDA modified matrix presented in General Program Memorandum # G95-1.

h. Clinical Testing

No clinical evaluations were performed or relied upon for a determination of substantial equivalence.

i. Conclusions

The information provided within this pre-market notification demonstrates that the *Dobbhoff™ Dual Port Feeding Tubes* have no difference that would affect the safety or effectiveness of the devices as compared to the predicate devices.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Debora Stapleton
Regulatory Affairs Manager
Covidien
15 Hampshire Street
MANSFIELD MA 02048

MAY 11 2012

Re: K112511
Trade/Device Name: DOBBHOFF™ Dual Port Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 27, 2012
Received: May 1, 2012

Dear Ms. Stapleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

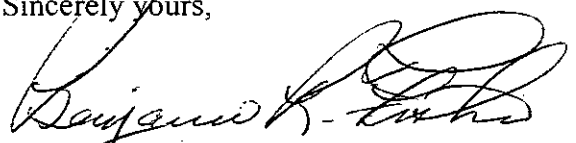
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K112511

Device Name: Dobbhoff Dual Port Feeding Tube

Indications For Use:

DOBBHOFF™ Dual Port Feeding Tubes, with and without Flow-Through Stylet, are for the administration of nutrition, fluids and medications by the naso-enteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chairman H-Bur for Benjamin Fisher

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112511